

What is claimed is:

1. A stabilized azithromycin composition comprising an intimate admixture of azithromycin and a stabilizing-effective amount of an antioxidant.
2. The azithromycin composition according to claim 1, wherein less than about 3.5% of the azithromycin is degraded on exposure to 55 °C for seven days.
3. The azithromycin composition according to claim 1, wherein less than about 1.25% of the azithromycin is degraded on exposure to 50 °C for 20 hours.
4. The azithromycin composition according to claim 1, wherein the intimate admixture is achieved by coprecipitation of the azithromycin and the antioxidant.
5. The azithromycin composition according to claim 1, wherein the intimate admixture is achieved by co-milling the azithromycin and the antioxidant.
6. The azithromycin composition according to claim 1, wherein the intimate admixture is achieved by compaction or slugging of the azithromycin and the antioxidant.
7. The azithromycin composition according to claim 1, wherein the azithromycin is azithromycin ethanolate monohydrate.
8. The azithromycin composition according to claim 1, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ascorbic acid, a pharmaceutically acceptable salt or ester thereof, and mixtures thereof.
9. The azithromycin composition according to claim 1, wherein the antioxidant is present in amount of from about 0.01% to about 10% by weight azithromycin.
10. The azithromycin composition according to claim 1, antioxidant is present in an amount of from about 0.1% to about 5% by weight azithromycin.
11. The azithromycin composition according to claim 1, wherein the antioxidant is butylated hydroxytoluene.
12. The azithromycin composition according to claim 1, wherein the antioxidant is sodium ascorbate.
13. A pharmaceutical formulation comprising the stabilized azithromycin composition of claim 1 and a carrier, wherein the pharmaceutical formulation is in a form selected from

the group consisting of a tablet, granulate, dragee, capsule, powder, solution, emulsion and suspension.

14. The pharmaceutical formulation according to claim 13, wherein the formulation is in a form of a tablet or capsule.

15. The pharmaceutical formulation according to claim 14, wherein the formulation is in the form of a tablet.

16. The pharmaceutical formulation according to claim 13, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ascorbic acid, a pharmaceutically acceptable salt or ester of one of these compounds, and mixtures thereof.

17. The pharmaceutical formulation according to claim 16, wherein the antioxidant is butylated hydroxytoluene.

18. The pharmaceutical formulation according to claim 16, wherein the antioxidant is present in an amount of from about 0.01% to about 10% by weight azithromycin.

19. The pharmaceutical formulation according to claim 16, wherein the antioxidant is present in an amount of from about 0.1% to about 5% by weight azithromycin.

20. The pharmaceutical formulation according to claim 13, wherein the stabilized azithromycin composition is made by dissolving azithromycin and an antioxidant in a solvent followed by evaporation of the solvent.

21. The pharmaceutical formulation according to claim 20, wherein the azithromycin is azithromycin ethanolate monohydrate.

22. A method for preparing a stabilized azithromycin composition comprising:
dissolving azithromycin and a stabilizing-effective amount of an antioxidant in a solvent; and co-precipitating azithromycin and antioxidant from said solvent to form a stabilized azithromycin composition.

23. The method of claim 22, further comprising recovering said stabilized azithromycin composition from said solvent.

24. The method according to claim 22, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ascorbic acid, a pharmaceutically acceptable salt or ester of one of these compounds, and

mixtures thereof, and wherein the antioxidant is present in an amount in the range of from about 0.5% to about 10% moles per mole of azithromycin.

25. The method according to claim 24, wherein the antioxidant is butylated hydroxytoluene.

5 26. A method of preparing a stabilized azithromycin composition comprising: dissolving azithromycin and a stabilizing-effective amount of an antioxidant in a first solvent to form a mixture; drying the mixture; redissolving the mixture in a second solvent; co-precipitating azithromycin and antioxidant from said solvent to form a stabilized azithromycin composition comprising an intimate admixture of azithromycin
10 and antioxidant.

27. The method of claim 26, further comprising recovering said stabilized azithromycin composition from said solvent.

28. A method of preparing a pharmaceutical formulation comprising granulating a stabilized azithromycin composition comprising an intimate admixture of azithromycin
15 and a stabilizing-effective amount of an antioxidant to form granules, followed by shaping said granules into a tablet.

29. The method of claim 28, wherein said granulating comprises wet granulation.

30. The method of claim 28, wherein said granulating comprises dry granulation.

31. The method of claim 30, wherein said dry granulation comprises roller
20 compaction.

32. The method of claim 31, wherein said dry granulation comprises slugging.

33. The method according to claim 28, further comprising coating the tablets.

34. The method of claim 33, wherein the tablets are coated with a coating comprising hydroxypropyl cellulose.

25 35. A method of treating a bacterial infection in a human or non-human animal in need of such treatment comprising administering to said human or non-human animal a pharmaceutical formulation comprising a stabilized azithromycin composition wherein said composition comprises an intimate admixture of azithromycin and a stabilizing-effective amount of an antioxidant.